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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,650	10/17/2000	Mike Krivoruchko		3571

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MEDTRONIC AVE, INC.
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,650

Applicant(s)

KRIVORUCHKO ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, drawn to stent delivery devices, classified in class 623, subclass 1.11.
 - II. Claim 15-19, drawn to methods of mounting a stent on a delivery device, classified in class 606, subclass 108.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as implanting a tracheal tube.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Catherine Maresh on February 25, 2002 a provisional election was made **without traverse** to prosecute the invention of Group I, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

3. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing. In particular, a drawing of the coupling member selectively coupling the valve relief to the outer shaft of claim 7 requires a drawing to facilitate understanding of the invention. Furthermore, the hemostatic valve (page 7, lines 6-11) is not shown in the drawings.

Claim Objections

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The second occurrence of claim 18 has been renumbered to claim 19.

Specification

5. The disclosure is objected to because of the following informalities: line 9 of page 9 contains an extra period.

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6. The use of the trademark, Tuohy-Borst, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of the claims as compared with the body of the claims appear inconsistent in scope such that it is unclear as to whether or not the stent is a positively required element to the invention. Should the stent be positively recited in the preamble, the examiner suggests the preamble of claim 1 be changed to read as ---A stent delivery system, the system comprising:--- for example.

9. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitations "a coupling member" and "a valve relief" are not clearly described in the specification.

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10. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitations "the stent stop" and "the radiopaque marker" lack proper antecedence rendering the claim indefinite.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 6, 8-12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Braunschweiler et al. (U.S. PN 5,484,444).

Braunschweiler et al. discloses a stent delivery device having inner and outer reciprocating shafts (2,3), stent receiving area (region B), tapered tip (15), handles with moveable knobs connected to both shafts for manipulating reciprocal motion (5,6), stent having plurality of segments at differing radial positions when unexpanded (1), stent stops (8,14), and radiopaque markers on the inner shaft located on the stent stops (8,14). See figures 1-4 and line 60 of column 3 to line 27 of column 5.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braunschweiler et al. (U.S. PN 5,484,444) in view of Lenker et al. (U.S. PN 5,683,451).

Braunschweiler et al. discloses a stent delivering device meeting the limitations of claims 2-5 as described above, except Braunschweiler et al. lacks a channel member defining a plurality of channels extending the length of the lumen between inner and outer shafts. Lenker et al. teaches a stent delivery device having channel members defining a plurality of channels along the length of the catheter body in order to provide more column strength while maintaining flexibility (see figures 13 and 14 and lines 30-40 of column 9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Braunschweiler et al. stent delivery device to include the channel members, as taught by Lenker et al., along the length of the catheter body in order to increase column strength while maintaining flexibility.

With further regard to claim 4, Lenker et al. does not expressly disclose a channel member providing eight channels. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a channel member defining eight channels because Applicant has not disclosed that a channel member defining eight channels provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with seven channels taught by Lenker et al. (see figure 13) because multiple channels provide sufficient column strength and flexibility. Furthermore, Applicant has stated in

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lines 16-17 on page 7 of the specification that "any suitable number of channels may be chosen".

Therefore, it would have been an obvious matter of design choice to further modify the stent delivery device of Braunschweiler et al. as modified by Lenker et al. to obtain the invention as specified in claim 4.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Braunschweiler et al. (U.S. PN 5,484,444) in view of Williams et al. (U.S. PN 5,391,172).

Braunschweiler et al. meets the limitations of claim 7 as described above, but lacks a coupling member for coupling a valve relief to the outer shaft. Williams et al. teaches a stent delivery system having a valve relief (not shown) attached to the outer sheath by coupling member (250) to prevent blood from collecting and coagulating within the annulus between the inner and outer catheters (see abstract and line 60 of column 3 to line 17 of column 4). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent delivery device taught by Braunschweiler et al. to include a coupling member for attaching a valve relief in order to prevent blood from collecting and coagulating within the annulus between the inner and outer catheters.

14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Braunschweiler et al. (U.S. PN 5,484,444) in view of Lange et al. (U.S. PN 6,036,682).

Braunschweiler et al. meets the limitations of claim 13 as described above, but lacks the specific disclosure of placing the radiopaque marker on the distal end of the outer shaft. Lange et al. teaches catheter for dilation of narrowed vessels having radiopaque markers on an outer shaft in order to assist the surgeon with viewing positions of the catheter or measuring internal dimensions (see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent delivery device taught by Braunschweiler et al. to include radiopaque markers, as taught by Lange et al., on an outer shaft in order to assist the surgeon with viewing position of the catheter or measuring internal dimensions.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Number 5,593,394 shows a catheter tube having inner and outer shafts with channel member creating eight channels for structural benefits.

U.S. Patent Numbers 5,328,469, 5,645,559, 5,782,855, and 5,843,090 disclose various stent delivery devices meeting various limitations of the claimed invention.

U.S. Patent Numbers 5,284,475, 5,466,230, 5,688,234, and 6,221,057 disclose various types of valves and fittings for proximal ends of catheters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number

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is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM
March 5, 2002



Paul B. Prebille
Primary Examiner